

Biopure Corporation (ticker: BPUR, exchange: NASDAQ) News Release - 10/30/2003

Biopure Updates Regulatory and Operating Plans

Conference Call Scheduled For 11:30 a.m. ET Today, October 30, 2003

CAMBRIDGE, Mass., Oct. 30 /PRNewswire-FirstCall/ -- Biopure Corporation (Nasdaq: BPUR) today announced its plan to respond by June 30, 2004, to the Food and Drug Administration's (FDA) questions regarding its biologic license application (BLA) for Hemopure (R) [hemoglobin glutamer - 250 (bovine)]. The company has adjusted its operating plan to reduce expenses and conserve cash while it completes its written response to the FDA.

Biopure applied for FDA approval to market the company's oxygen therapeutic, Hemopure, in the United States for the treatment of acutely anemic adult patients undergoing orthopedic surgery and for the elimination or reduction of red blood cell transfusions in these patients.

During the past two months the company has had several substantive interactions with the FDA to clarify the Agency's questions. Many of Biopure's responses have been completed. However, some require the retrieval of source medical documents and/or historical blood transfusion data from clinical trial sites in various countries, which will take several months to complete.

Biopure has engaged David Zuchero, President of Chesapeake Regulatory Group (CRG), as its interim senior regulatory officer to direct the FDA response activities of Biopure's in-house regulatory team, the CRG team and other external consultants. He replaces Howard Richman, former Senior Vice President of Regulatory and Operations, who has left Biopure to pursue other interests. A 25-year industry veteran, Zuchero has provided strategic counsel and managed several major regulatory submissions during his 13-year tenure at CRG and in his previous regulatory positions at Pharmakinetix Laboratories, Inc., Chelsea Laboratories, Inc., and Ayerst (now Wyeth-Ayerst) Laboratories. He is a certified regulatory affairs expert, attorney and former microbiologist.

Biopure has also implemented cost reductions designed to minimize its ongoing cash burn, which include reducing the workforce by approximately 30 percent and decreasing forecast manufacturing expenses for fiscal 2004. These measures represent overall anticipated savings of approximately \$12 million in fiscal 2004, despite higher costs associated with FDA response activities. The company is in the process of renewing a standby equity distribution agreement to provide up to \$15 million as needed. Biopure's current cash and anticipated Oxyglobin revenues together with this standby facility are expected to fund operations through December 2004.

"In the best interests of our shareholders, today we've taken the steps necessary to more efficiently run our business while we complete our comprehensive response to all of the FDA's questions," said Biopure President and CEO Thomas A. Moore. "We view the Agency's questions as a 'roadmap' to approval and have set a conservative, achievable target date for our response. We remain enthusiastically committed to commercializing Hemopure in the United States as expeditiously as possible."

Biopure's updated plans continue to include clinical development of Hemopure for other potential indications. A Phase II cardiac revascularization trial in patients undergoing elective percutaneous coronary intervention (e.g., angioplasty, stent) is scheduled to begin enrolling patients in Europe this year, and a Phase II trauma trial co-sponsored by the U.S. Army and Navy is anticipated in 2004. These new trials are unrelated to the current Hemopure BLA.

Conference Call

Biopure President and CEO Thomas A. Moore will discuss the company's regulatory and operating plans in a conference call and webcast on Thursday, October 30, 2003, at 11:30 a.m. ET. The dial-in numbers are 1-800-535-9844 (US/Canada) and 1-706-634-7089 (International). A live audio webcast of the conference call will be available from the investor section of Biopure's web site at www.biopure.com and will be archived for at least one week. The webcast can also be heard by individual investors at www.companyboardroom.com and by institutional investors who subscribe to StreetEvents at www.streetevents.com. An audio replay of the conference call will be available at approximately 2:30 p.m. ET, October 30, 2003, until midnight ET, November 7, 2003. To access the replay, dial 1-800-642-1687 (US/Canada) or 1-706-645-9291 (International/Local) and reference conference ID number 3753466.

Biopure Corporation

Biopure Corporation, headquartered in Cambridge, Mass., is a leading developer, manufacturer and marketer of oxygen therapeutics, a

new class of pharmaceuticals that are intravenously administered to deliver oxygen to the body's tissues. Hemopure(R) [hemoglobin glutamer - 250 (bovine)], or HBOC- 201, is approved in South Africa for the treatment of adult surgical patients who are acutely anemic and for eliminating, delaying or reducing the need for allogenic red blood cell transfusion in these patients. Biopure's veterinary product Oxyglobin(R) [hemoglobin glutamer - 200 (bovine)], or HBOC-301, the only oxygen therapeutic approved by the FDA and the European Commission, is indicated for the treatment of anemia in dogs.

The content of this press release does not necessarily reflect the position or the policy of the U.S. Government or the Department of Defense, and no official endorsement should be inferred. Completion of the pivotal RESUS clinical trial of Hemopure in trauma is contingent upon further funding. Statements in this press release that are not strictly historical may be forward-looking statements. There can be no assurance that Biopure Corporation will be able to commercially develop its oxygen therapeutic products, that necessary regulatory approvals will be obtained, that anticipated milestones will be met in the expected timetable, that any clinical trials will be successful, or that any approved product will find market acceptance and be sold in the quantities anticipated. Actual results may differ from those projected in forward-looking statements due to risks and uncertainties that exist in the company's operations and business environment. These risks include, without limitation, the company's stage of product development, history of operating losses and accumulated deficits, and uncertainties and possible delays related to clinical trials, regulatory approvals, possible healthcare reform, manufacturing capacity, marketing, market acceptance, competition and the availability of sufficient financing to support operations. The company undertakes no obligation to release publicly the results of any revisions to these forward-looking statements to reflect events or circumstances arising after the date hereof. A full discussion of Biopure's operations and financial condition, and specific factors that could cause the company's actual performance to differ from current expectations, can be found on the company's Web site at www.biopure.com/corporate/legal/home_legal.htm and in the company's filings with the U.S. Securities and Exchange Commission, which can be accessed in the EDGAR database at the SEC Web site, www.sec.gov, or through the Investor section of Biopure's Web site, www.biopure.com.

* \$4,502,900 is from Grant DAMD17-02-1-0697. The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office.

Contact: Douglas Sayles (617) 234-6826
Tom Nealon (617) 234-6873
Biopure Corporation IR@biopure.com

SOURCE Biopure Corporation
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CONTACT: Douglas Sayles, +1-617-234-6826, or Tom Nealon, +1-617-234-6873 both of Biopure Corporation, IR@biopure.com

Web site: <http://www.biopure.com>
(BPUR)